

**Nelson, Bettie L**  
**From:** Gomm, Willy  
**Sent:** Thursday, September 13, 2001 4:51 AM  
**To:** Nelson, Bettie L  
**Cc:** Reininghaus, Wolf  
**Subject:** DMAU Proposal

Dear Bettie,

We all feel deeply shocked about the terrible terroristic attacks that hit the United States and we hope very much that none of your family, friends or colleagues has been affected. Although also my faculty of thought and concentration is severely disturbed due to these terrible incidents I will try summarize my comments on your proposal.

Paragraph 1 and 2: Purpose and Rationale:

In general it is a good direction to extend the data analysis of the external studies. The analyses performed by the CROs are in my view only a basis; additional explanatory evaluations within the studies and across studies evaluations could be very helpful to better understand the results.

Paragraph 4: Housing...

SAS is definitely the right choice for data analysis. Our standard reporting and analysis system is currently not based on SAS, we use it in addition to the tool we developed in-house. But we plan to switch to an SAS based system in future, not short term, but medium term. With respect to data management (data base) I have no experience with SAS. We currently use ORACLE and we will continue to use it in future, with SAS as a kind of front-end analysis tool.

Paragraph 5: Accessibility...

At INBIFO all users in the scientific units are allowed to use the data for the (statistical) analyses they need for their work. This means the read access is not so restricted as you plan. Our colleagues can do the analyses on their own or can ask us either to help them or to perform the analyses for them.

Resources used at INBIFO

As you know the Information Systems (IS) unit is responsible for all IS related tasks as well as for the statistical evaluations performed by us or supported by us in case they are performed in the scientific units. I estimate that about the equivalent of 1.5 IS employee is involved in the statistical evaluations, I am not able to estimate to resources needed in addition in the scientific units. To illustrate the workload we have, I made some estimations: In 2000, we have significantly contributed to the analyses of 10 90-day inhalation studies, 12 Ames studies, 5 cytotoxicity studies, 4 Analytical chemistry studies, 2 mouse lymphoma assays, 11 other miscellaneous studies, and 1 very complex study, the RASS/DEE life time study on rats. The quite low numbers of cytotoxicity and chemistry studies reflects the fact that these units do a lot of evaluations by themselves. In addition a significant part of my time was spent for expert opinions on statistical questions and general statistical advice and planning like TES.

I hope my remarks are helpful for you.

Best regards

PM3006313561

Willy

PM3006313562